PART 801

SECTION F

X-RAYS IN THE HEALING ARTS

801.F.1 Scope. This section establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with Mississippi statutes to engage in the healing arts or veterinary medicine. The provisions of this section are in addition to, and not in substitution for, other applicable provisions of these regulations.

801.F.2 Definitions. As used in this section, the following definitions apply:

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy[1/] affording the same attenuation, under specified conditions, as the material in question.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[1/] or other materials having equivalent attenuation.

"Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also "Phototimer").

"Barrier" (See "Protective barrier").

"Beam axis" means a line from the source through the centers of the x-ray fie1ds.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

1/The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"C-Arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

"Certified system" means any x-ray system comprised totally of certified components.

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

"Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a sample population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{X}} = \frac{1}{\overline{X}} \left[\sum_{i=1}^{n} \frac{(X_i - \overline{X})^2}{n-1} \right]^{1/2}$$

where

s	=	Estimated standard deviation of the population.
$\overline{X}$	=	Mean Value of observations in sample.
X_i	=	$_i$th observation in sample.
n	=	Number of observations in sample.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for setting the technique factors.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" (See "Computed tomography").

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Detector" (See "Radiation detector").

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (See "X-ray equipment").

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field."

"Filter" means material placed in the useful beam to absorb preferentially selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot" means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

"General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"HVL" (See "Half-value layer").

"Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"Kilovolt (kV) [kilo electron volt (keV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons].

"Kilovolts peak" (See "Peak tube potential").

"kVp" (See "Peak tube potential").

"kWs" means kilowatt second.

"Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions as lead.

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(1) the useful beam; and

(2) radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Light field" means the area illuminated by light, being the locus of points at which the illumination exceeds a specific or specified level, simulating the radiation field.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100\ (V_n - V_1)/V_1$
where
V_n = No-load line potential and
V_1 = Load line potential.

"mA" means milliampere.

"mAs" means milliampere second.

"Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

"Mobile x-ray equipment" (See "X-ray equipment").

"Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.

"PBL" See "Positive beam limitation."

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

"Phototimer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

"PID" (See "Position indicating device").

"Portable x-ray equipment" (See "X-ray equipment").

"Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semiautomatic adjustment of an x-ray beam to the selected image receptor size, whereby exposures cannot be made without such adjustment.

"Primary protective barrier" (See "Protective barrier").

"Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.

(2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Qualified expert" means an individual who has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

"Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from x-ray photons.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

"Secondary protective barrier" (See "Protective barrier").

"Shutter" means a device attached to the tube housing assembly which can totally intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SID" (See "Source-image receptor distance").

"Source" means the focal spot of the x-ray tube.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"SSD" means the distance between the source and the skin entrance plane of the patient.

"Stationary x-ray equipment" (See "X-ray equipment").

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation:

(1) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(2) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) for CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) for CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) for all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through a body.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"X-ray exposure control" means a device, switch, button, or other similar means by which an operator initiates and/or terminates the radiation exposure.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(2) "Portable x-ray equipment" means x-ray equipment designed to be hand carried.

(3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray subsystem" means any combination of two or more components of an x-ray system.

"X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

801.F.3 General and Administrative Requirements.

(a) Radiation Safety Requirements. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the x-ray system(s).

(1) An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic purposes (if so directed by the Agency).

(2) Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. See Appendix A for a list of subject matters pertinent to this requirement. The Agency may use interview, observation and/or testing to determine compliance.

(3) A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

(i) patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

(ii) type and size of the film or screen-film combination to be used;

(iii) type and focal distance of the grid to be used, if any;

(iv) source to image receptor distance to be used (except for dental intraoral radiography); and

(v) type and location of placement of patient shielding (i.e., gonad, etc.) to be used.

(4) The registrant of a facility shall establish and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for human patients who cannot be moved out of the room, only the staff and ancillary personnel, or other persons, required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(i) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material.

(ii) The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material.

(iii) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material, or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(i) exposure of an individual for training, demonstration, or other non-healing-arts purposes; and

(ii) exposure of an individual for the purpose of healing arts screening except as authorized by 801.F.3(a)(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

(i) mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 801.F.3(a)(4), shall list individual projections where holding devices cannot be utilized;

(ii) written safety procedures, as required by 801.F.3(a)(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(iii) the human holder shall be instructed in personal radiation safety and protected as required by 801.F.3(a)(5);

(iv) no individual shall be used routinely to hold film or patients;

(v) in those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material;

(vi) when an animal must be held by an individual during an exposure, that individual shall be protected with appropriate shielding devices, such as leaded aprons and gloves, and shall be positioned such that no part of his or her body shall be struck by the useful beam; and

(vii) each facility must have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(i) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of standard film packets for intraoral use in dental radiography.

(ii) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(iii) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

(iv) X-ray systems subject to 801.F.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters except for veterinary systems.

(v) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast the grid shall:

(a) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray.

(b) If of the focused type, be of the proper focal distance for the SID's being used.

(10) All individuals who are associated with the operation of an x-ray system are subject to the requirements of 801.D.101, 801.D.102, and 801.D.202 of these regulations. In addition:

(i) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(a) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

(b) The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by 801.D.401 of these regulations. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

(ii) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing Arts Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix B of this section. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

(12) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Agency:

(i) model and serial numbers of all major components, and user's manuals for those components;

(ii) tube rating charts and cooling curves;

(iii) records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s); and

(iv) a copy of all correspondence with this Agency regarding that x-ray system.

(13) X-Ray Log. Each facility shall maintain an x-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

(14) A sign shall be posted in a conspicuous area so as to be easily seen by the patient to the effect that if there is a pregnancy or the possibility of a pregnancy, the physician should be notified. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate protective measures are taken.

(b) X-ray Film Processing Facilities and Practices. Each installation using a radiographic x-ray system and using analog image receptors (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film:

(i) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

(ii) The temperature of solutions in the tanks shall be maintained within the range of 60 °F to 8O °F (16 °C to 27 °C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the time-temperature chart on the next page:

Time-Temperature Chart

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 1/2
25.0	77	2 1/2
24.4	76	3
23.9	75	3
23.3	74	3 1/2
22.8	73	3 1/2
22.2	72	4
21.7	71	4
21.1	70	4 1/2
20.6	69	4 1/2
20.0	68	5
19.4	67	5 1/2
18.9	66	5 1/2
18.3	65	6
17.8	64	6 1/2
17.2	63	7
16.7	62	8
16.1	61	8 1/2
15.6	60	9 1/2

(iii) Devices shall be utilized which will:

(a) Indicate the actual temperature of the developer; and

(b) Signal the passage of a preset time appropriate to the developing time required.

(2) Automatic Processors and Other Closed Processing Systems:

(i) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the chart on the next page:

Developer Temperature (Degrees)		Minimum Immersion Time:* (Seconds)
°C	°F	
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

*Immersion time only, no crossover time included.

(ii) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

(3) Other Requirements

(i) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(ii) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1

(0.02 for mammography) when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

(iii) Darkrooms typically used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed.

(iv) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(v) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

(vi) Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

(vii) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

801.F.4 General Requirements for all Diagnostic X-Ray Systems. In addition to other requirements of this section, all diagnostic x-ray systems shall meet the following requirements:

(a) Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(b) Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(c) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 uC/kg) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If leakage technique factors cannot be set on the control panel, then compliance shall be determined by measuring leakage at maximum kVp and an appropriate mAs.

(d) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 uC/kg)

in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(e) Beam Quality.

(1) Half-value Layer.

(i) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

X-ray tube voltage (kilovolt peak)			Minimum HVL (mm of Al)	
Designed operating range		Measured operating potential	Specified dental systems	Other X-ray systems
Below 50	----------	30	N/A	0.3
		40	N/A	0.4
		49	N/A	0.5
50 to 70	----------	50	1.5	1.2
		60	1.5	1.3
		70	1.5	1.5
Above 70	----------	71	2.1	2.1
		80	2.3	2.3
		90	2.5	2.5
		100	2.7	2.7
		110	3.0	3.0
		120	3.2	3.2
		130	3.5	3.5
		140	3.8	3.8
		150	4.1	4.1

(ii) For capacitor energy storage equipment, compliance with the requirements of 801.F.4(e) shall be determined with the maximum quantity of charge per exposure. This will be deemed to have been met if a mAs of 5-10 has been used.

(iii) The required minimal half-value-layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by 801.F.4(e)(1) is in the useful beam for the given kVp which has been selected.

(f) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

(g) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

(h) Technique Indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirements of 801.F.4(h)(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(i) Locks. All position locking, holding, and centering devices on x-ray system components shall function as intended.

801.F.5 Fluoroscopic X-Ray Systems. All fluoroscopic x-ray systems shall be image intensified and meet the following requirements:

(a) Limitation of Useful Beam.

(1) Primary Barrier.

(i) The fluoroscopic imaging assembly used shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

(ii) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic Beam Limitation.

(i) For certified fluoroscopic systems, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(ii) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

(iii) For uncertified fluoroscopic systems without a spot film device, the requirements of 801.F.5(a)(2)(i) apply.

(iv) Other requirements for fluoroscopic beam limitation:

(a) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustments of the x-ray field.

(b) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less.

(c) If provided, stepless adjustment shall provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less.

(d) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(e) For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(3) Spot Film Beam Limitation. Spot-film devices which are certified components shall meet the following additional requirements:

(i) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

(ii) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters.

(iii) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

(iv) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic x-ray field size adjustments required in 801.F.5(a)(2), and (3) that means:

(i) shall be designed for use only in the event of system failure;

(ii) shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

(iii) shall be clearly and durably labelled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

(b) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(c) Exposure Rate Limits.

(1) Entrance Exposure Rate Allowable Limits.

(i) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images, or

(b) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(ii) Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images, or

(b) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(iii) Compliance with the requirements of 801.F.5(c) shall be determined as follows:

(a) If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(b) If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the

beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(c) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(d) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the center line of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam limiting device or spacer no closer than 15 centimeters to the center line of the x-ray table.

(2) Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both maximum and typical values, as follows.[2/]

(i) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

(ii) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 801.F.3(a)(12)(iii). The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

(iii) Conditions of periodic measurement of maximum entrance exposure rate are as follows:

(a) the measurement shall be made under the conditions that satisfy the requirements of 801. F.5(c)(1)(iii);

2/Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.

(b) the kVp, mA, and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate; and

(c) the x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system.

(iv) Conditions of periodic measurement of typical entrance exposure rate are as follows:

(a) the measurement shall be made under the conditions that satisfy the requirements of 801.F.5(c)(1)(iii);

(b) the kVp and mA shall be typical of clinical use of the x-ray system; and

(c) the x-ray system(s) that incorporates automatic exposure rate control shall have an appropriate phantom placed in the useful beam to produce a milliamperage and/or kilovoltage typical of the use of the x-ray system.

(d) Barrier Transmitted Radiation Rate Limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier shall not exceed 2 milliroentgens (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring Compliance of Barrier Transmission.

(i) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the

tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

(iv) Compression devices and movable grids shall be removed from the useful beam during the measurement.

(e) Indication of Potential and Current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

(f) Source-to-Skin Distance. The SSD shall not be less than:

(1) 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(2) 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

(3) 30 centimeters on all mobile fluoroscopes; and

(4) 20 centimeters for all mobile fluoroscopes used for specific surgical procedures.

(g) Fluoroscopic Timer.

(1) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(h) Control of Scattered Radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the table top unless that individual:

(i) is at least 120 centimeters from the center of the useful beam; or

(ii) the radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 801.F.3(a)(1)(5).

(3) The Agency may grant exemptions to 801.F.5(h)(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption. See Appendix C for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

(i) Spot Film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of 801.F.6(d) when operating in the spot film mode.

(j) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 801.F.5(a), 801.F.5(c), 801.F.5(d), and 801.F.5(g) provided that:

(1) such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(2) systems which do not meet the requirements of 801.F.5(g) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

801.F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinarian, Computed Tomography, or Mammography Systems.

(a) Beam Limitation. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam-limiting device has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film, (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

(1) General Purpose Stationary and Mobile X-Ray Systems.

(i) The use of a variable-field beam limiting device providing stepless, independent adjustment of at least two dimensions of the x-ray field is required.

(ii) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(iii) The Agency may grant an exemption on noncertified x-ray systems to 801.F.6(a)(1)(i) and (ii) provided the registrant makes a written application for such exemption and in that application:

(a) demonstrates it is impractical to comply with 801.F.6 (a)(1)(i) and (ii); and

(b) the purpose of 801.F.6(a)(1)(i) and (ii) will be met by other methods.

(2) Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of 801.F.6(a)(1), all stationary general purpose x-ray systems shall meet the following requirements:

(i) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent.

(ii) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

(iii) Indication of field size dimension and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-Ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Radiographic Systems Other Than Those Designated in 801.F.6(a)(1),(2), and (3).

(i) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(ii) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

(iii) 801.F.6(a)(4)(i) and (ii) may be met with a system that meets the requirements for a general purpose x-ray system as specified in 801.F.6(a)(1) or, when alignment means are also provided, may be met with either:

(a) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(b) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(b) Radiation Exposure Control

(1) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a positive action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such a positive action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure Termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(i) Manual exposure control. An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("dead-man" switch) except for:

(a) exposure of 1/2 second or less; or

(b) during serial radiography when means shall be

provided to permit completion of any single exposure of the series in process.

(ii) Automatic exposure control. When an automatic exposure control is provided:

(a) indication shall be made on the control panel when this mode of operation is selected;

(b) if the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(c) the minimum exposure time for all equipment other than that specified in 801.F.6(b)(2)(ii)(b) shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;

(d) either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except that when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(e) a visible signal shall indicate when an exposure has been terminated at the limits required by 801.F.6(b)(ii)(d), and manual resetting shall be required before further automatically timed exposures can be made.

(3) Exposure Indication. Means shall be provided for visual indication of x-ray production observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(4) Exposure Duration (Timer) Reproducibility. With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (T_{max}) and the minimum exposure time (T_{min}) shall be less than or equal to 10% of the average exposure time ($\overline{T}$), when four timer tests are performed:

$$(T_{max} - T_{min}) \leq 0.10\ \overline{T}$$

(5) Exposure Control Location. The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

(6) Operator Protection, Except Veterinary Systems.

(i) Stationary systems. Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

(ii) Mobile and portable systems. Mobile and portable x-ray systems which are:

(a) used continuously for greater than one week in the same location, i.e., a room or suite shall be considered as stationary systems under 801.F.6(b)(6)(i); and

(b) used for less than one week in the same location shall be provided with either a protective barrier at least 6.5 feet (2 m) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 12 feet (3.7 m) from the tube housing assembly during the exposure.

(7) Operation Protection for Veterinary Systems. All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a 6.5 foot (2 m) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 12 feet (3.7 m) from the tube housing assembly during exposures.

(c) Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

(d) Exposure Reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control (phototiming) systems, the coefficient of variation of exposure for both manual and phototimed systems shall not exceed 0.05. This requirement shall be deemed to have been met, if, when four exposures are made at identical technique factors, the difference between the maximum exposure (E_{max}) and the minimum exposure (E_{min}) shall be less than or equal to 10% of the average exposure ($\overline{E}$):

$$(E_{max} - E_{min}) \leq 0.10\ \overline{E}$$

(e) Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 uC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(f) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.

(g) Linearity, Uncertified X-Ray Systems Only. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliampere-seconds product mR/mAs (C/kg/mAs) obtained at any two tube current settings shall not differ by more than 0.10 times their sum. This is:

$$| \overline{X_1} - \overline{X_2} | \leq 0.10 (\overline{X_1} + \overline{X_2})$$

where $\overline{X_1}$ and $\overline{X_2}$ are the average mR/mAs (C/kg/mAs) values obtained at any two tube current settings.

(2) Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliampere-seconds product mR/mAs (C/kg/mAs) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$$| \overline{X_1} - \overline{X_2} | \leq 0.10 (\overline{X_1} + \overline{X_2})$$

where $\overline{X_1}$ and $\overline{X_2}$ are the average mR/mAs (C/kg/mAs) values obtained at any two mAs selector settings.

(3) Measuring compliance. Determination of compliance shall be based on 4 exposures, of no less than 0.05 seconds each, taken within a time period of one hour, at each of the two settings.

These two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(h) Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$| \overline{X_1} - \overline{X_2} | \leq 0.10 (\overline{X_1} + \overline{X_2})$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average mR/mAs (C/kg/mAs) values obtained at each of 2 consecutive tube current settings.

(2) Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

(i) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 cm shall be equal to or less than 5 centimeters by 5 centimeters.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

(3) Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 801.F.6(a)(1) and 801.F.6(g)(2).

(4) Field Limitation and Alignment on Stationary General Purpose X-Ray Systems. For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c):

(i) Positive beam limitation (PBL) shall be provided whenever all the following conditions are met:

(a) The image receptor is inserted into a permanently mounted cassette holder;

(b) The image receptor length and width are each less than 50 centimeters;

(c) The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(d) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;

(e) Neither tomographic nor stereoscopic radiography is being performed; and

(f) The PBL system has not been intentionally overridden. This override provision is subject to 801.F.6(h)(4)(iii).

(ii) Positive beam limitation (PBL) shall prevent the production of x-rays when:

(a) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by 801.F.6(h)(4)(v), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

(b) The sum of the length and width differences as stated in 801.F.6 (h)(4)(ii)(a) without regard to sign exceeds 4 percent of the SID.

(iii) If a means of overriding the positive beam limitation (PBL) system exists, that means:

(a) Shall be designed for use only in the event of PBL system failure or if the system is being serviced; and

(b) If in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator,

(1) shall require that a key be utilized to defeat the PBL;

(2) shall require that the key remain in place during the entire time the PBL system is overridden; and

(3) shall require that the key or key switch be clearly and durably labelled as follows:

FOR X-RAY FIELD LIMITATION
SYSTEM FAILURE

(iv) Compliance with 801.F.6(g)(4)(ii) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 801.F.6(g)(4)(i) are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(v) The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

(vi) The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in 801.F.6(g)(4)(ii), then any change of image receptor size or SID must cause the automatic return.

(5) Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(i) Tube Stands for Portable X-Ray Systems. A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures.

801.F.7 Intraoral Dental Radiographic Systems. In addition to the provisions of 801.F.3 and 801.F.4, the requirements of 801.F.7 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 801.F.6.

(a) Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to
not less than:

(1) 18 centimeters if operable above 50 kVp; or

(2) 10 centimeters if not operable above 50 kVp.

(b) Field Limitation.

(1) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field such that the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

(2) An open ended PID (position indicating device) shall be used on new dental x-ray equipment purchased after the effective date of these regulations.

(c) Radiation Exposure Control for Certified and Noncertified Systems.

(1) Exposure Initiation.

(i) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

(ii) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure Termination.

(i) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(ii) An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 1/2 second or less.

(iii) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(3) Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(4) Exposure Duration (Timer) Reproducibility. With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (T_{max}) and the minimum exposure time (T_{min}) shall be less than or equal to 10% of the average exposure time ($\overline{T}$), when four timer test are performed:

$$(T_{max} - T_{min}) \leq 0.10\ \overline{T}$$

(5) Exposure Control Location and Operation Protection.

(i) Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

(ii) Mobile and portable x-ray systems which are:

(a) used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 801.F.7(c)(5)(i); and

(b) used for less than one week in the same location, shall be provided with either a protective barrier at least 6.5 feet (2m) high for operator protection, or means to allow the operator to be at least 12 feet (3.7 m) from the tube housing assembly while making exposures.

(d) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made within a period of one hour at identical technique factors, the difference between the maximum exposure value (E_{max}) and the minimum exposure value (E_{min}) shall be less than or equal to 10% of the average exposure ($\overline{E}$):

$$(E_{max} - E_{min}) \leq 0.10\ \overline{E}$$

(e) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated millampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$| \overline{X_1} - \overline{X_2} | \leq 0.10\ (\overline{X_1} + \overline{X_2})$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average mR/mAs (C/kg/mAs) values obtained at each of 2 consecutive tube current settings.

(f) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.

(g) kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

(h) Administrative Controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID shall not be hand held during an exposure.

(3) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 801.F.7(b).

(4) Dental fluoroscopy without image intensification shall not be used.

801.F.8 Veterinary Medicine Radiographic Installations.

(a) Equipment.

(1) The protective tube housing shall be equivalent to the requirements of 801.F.4(c).

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(4) A device shall be provided to terminate the exposure after a preset time or exposure.

(5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83 m) from the animal during all x-ray exposures.

(b) Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 801.D.101, 801.D.104, and 801.D.105 of these regulations.

(c) Operating Procedures.

(1) The operator shall stand well away from the useful beam and the animal during radiographic exposures.

(2) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

801.F.9 Computed Tomography X-Ray Systems.

(a) Definitions. In addition to the definitions provided in 801.A.2 and 801.F.2 of these regulations, the following definitions shall be applicable to 801.F.9:

"Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\ dz$$

where:

z	=	Position along a line perpendicular to the tomographic plane.
D(z)	=	Dose at position z.
T	=	Nominal tomographic section thickness.
n	=	Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:

u_x	=	Linear attenuation coefficient of the material of interest.
u_w	=	Linear attenuation coefficient of water.
$(CTN)_x$	=	CTN of the material of interest.
$(CTN)_w$	=	CTN of water.

"CS" (See "Contrast scale").

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 801.F.2.

"CTDI" (See "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number").

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k\ (\mu_x - \mu_w)}{\mu_w}$$

where:

k	=	A constant[3/]
u_x	=	Linear attenuation coefficient of the material of interest.
u_w	=	Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

"Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{\mu_w}$$

where:

CS	=	Contract scale.
u_w	=	Linear attenuation coefficient of water.
s	=	Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Picture element" means an elemental area of a tomogram.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

3/The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(b) Requirement for Equipment.

(1) Termination of Exposure.

(i) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

(ii) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 801.F.9(b)(1)(i).

(iii) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

(2) Tomographic Plane Indication and Alignment.

(i) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plan offset from the tomographic plane.

(ii) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

(iii) If a device using a light source is used to satisfy 801.F.9(b)(2)(i) or (ii), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam-On and Shutter Status Indicators and Control Switches.

(i) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(ii) Each emergency button or switch shall be clearly labelled as to its function.

(4) Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 801.F.4(c).

(6) Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(7) Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.

(i) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

(ii) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(iii) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical

starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(iv) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

(c) Facility Design Requirements.

(1) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing Systems.

(i) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(ii) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

(d) Surveys Measurements, Spot Checks and Operatinq Procedures.

(1) Surveys.

(i) All CT x-ray systems installed after the effective date of these regulations and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(ii) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Agency upon request.

(2) Radiation Measurements.

(i) The measurements of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert.

(ii) The measurement of the radiation output of the CT x-ray system shall be performed annually and after any change or replacement of components which could cause a change in the radiation output.

(iii) The measurement of the radiation output of the CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.

(iv) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(a) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl-methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

(b) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

(c) Any effects on the doses measured to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(d) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(v) The measurement of the radiation output shall be required for each type of head, body, or whole-body scan performed at the facility.

(vi) Measurement of the radiation output shall meet the following requirements:

(a) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic

thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.

(b) The CTDI[4/] along the two axes specified in 801.F.9(d)(2)(iv)(b) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

(c) The spot checks specified in 801.F.9(d)(3) shall be made.

(vii) Procedures for the measurement of radiation output shall be in writing. Records of measurements performed shall be maintained for inspection by the Agency.

(3) Spot Checks.

(i) The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

(ii) The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

(iii) All spot checks shall be included in the measurement required by 801.F.9(d)(2) and at time intervals and under system conditions specified by a qualified expert.

(iv) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform measurements required by 801.F.9(d)(2). The images shall be retained, until a new measurement is performed, in two forms as follows:

(a) photographic copies of the images obtained from the image display device; and

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4/For the purpose of determining the CTDI, the manufacturer's statements as to the nominal tomographic section thickness for that particular system may be utilized.

(b) images stored in digital form on a storage medium compatible with the CT x-ray system.

(v) Written records of the spot checks performed shall be maintained for inspection by the Agency.

(4) Operating Procedures.

(i) The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

(ii) Information shall be available at the control panel regarding the operation of the system and measurements of radiation output. Such information shall include the following:

(a) dates of the latest measurements and spot checks and the location within the facility where the results of those tests may be obtained;

(b) instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(c) the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(d) a current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

(iii) If the measurement or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those permitted by established written instructions of the qualified expert.

801.F.10 Mammography X-Ray Systems.

(a) Equipment Standards.

(1) System Design. The x-ray system shall be specifically designed for mammography.

(2) Image Receptor. The image receptor systems and their individual components shall be specifically designed for or appropriate for mammography.

(3) Target/Filter. The x-ray system must have the capability of providing kVp/target/filter combinations appropriate to image receptor systems meeting the requirements of 801.F.10(a)(2).

(4) Beam Quality.

(i) When used with screen-film image receptors, and the contribution to filtration made by the compression device is included, the useful beam shall have a half-value layer (HVL) between the values of: measured kVp/100 and measured kVp/100 + 0.1 millimeters aluminum equivalent.

(ii) For Xeroradiography using a kVp in the range of 35-50, the HVL of the useful beam with the compression device in place shall be at least 1.2 mm aluminum equivalent.

(iii) For all other imaging systems, the HVL shall not be less than that specified in 801.F.4(e).

(5) Resolution. The combination of focal spot size, source-to-image distance and magnification shall produce a radiograph with a resolution of at least 12.5 cycles per millimeter at an object-to-image receptor distance of five centimeters. This standard applies to the routine mammographic film being utilized at the facility. Compliance shall be deemed to have been met if AAPM Report No. 29, Table 3-3 (See Section F, Appendix D) is followed.

(6) Compression.

(i) The x-ray system shall be capable of compressing the breast with a force of at least 25 pounds and the maximum force shall be no greater than 40 pounds.

(ii) To within ± 1% of the source-to-image distance, the chest wall edge of the compression paddle must be aligned with the chest wall edge of the image receptor when the image receptor is placed in normal imaging position.

(7) System Capabilities. A mammographic x-ray system utilizing screen-film image receptors shall have:

(i) the capability of using anti-scatter grids which are:

(a) specifically designed for mammography;

(b) integral to the x-ray system; and

(c) available for all image receptor sizes.

(ii) the capability of automatic exposure control for systems installed after the effective date of these regulations.

(8) Milliampere-second Read-out Accuracy. All mammographic x-ray systems shall indicate, or provide the means of determining, the mAs resulting from each exposure made with automatic exposure control. The accuracy of the mAs read-out shall be within ± 10% of the actual mAs delivered.

(9) Transmission. For x-ray systems manufactured after September 5, 1978, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(10) Collimation.

(i) The mammographic system shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in 801.F.6(a)(4)(iii). When the beam- limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure, and the SID may vary, the SID indication specified in 801.F.6(a)(4)(iii)(a) and (b) shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for use on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(ii) The misalignment for the chest-wall edge of the collimator light field with the chest-wall edge of the x-ray beam shall not exceed 2% of the SID. The edge of the x-ray beam on the other three sides shall not exceed the edge of the light field on those sides.

(11) Accuracy of kVp. The accuracy of the indicated kVp shall be no less than ± 2 kVp.

(12) Automatic Exposure Control Performance. See 801.F.6(d). In addition, those mammographic systems operating with automatic exposure control shall be able to maintain film

density to within ± 0.3 OD of the average OD over the range of clinically used kVps, for phantom thicknesses of 2 centimeters to 6 centimeters.

(13) Radiation Output Minimum. At a kVp of 28, the mammographic system shall be capable of generating at least 8 mR/mAs and at least 800 mR/second, measured at a point 4.5 centimeters from the surface of the patient support device when the SID is at its maximum.

(14) Screen-film Contact. Cassettes shall not be used for mammography if one or more large areas (>1 cm) of poor contact can be seen in a 30-40 mesh test.

(15) Image Quality. The minimum image quality achieved at a mammographic facility shall be the ability to observe the image of a 0.75 mm fiber, 0.32 mm speck group, and a 0.75 mm mass from an ACR phantom or equivalent on the standard mammographic film in use in a facility. No mammograms shall be taken on patients if this minimum is not met.

(16) Dose. The mean glandular dose for one craniocaudal view of a 4.5 cm (1.8 inch) compressed breast, composed of 50 percent adipose/50 percent glandular tissue, shall not exceed the following values:

(i) 100 millirads (1 milligray) for non-grid screen - film systems.
(ii) 300 millirads (3 milligray) for screen-film systems.
(iii) 400 millirads (4 milligray) for Xerography systems.

(b) Quality Assurance.

(1) Quality Assurance Program Required. The registrant shall have a written, ongoing equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic x-ray imaging system, to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement include:

(i) conducting or training others to conduct equipment performance monitoring functions;

(ii) analyzing the monitoring results to determine if there are problems requiring correction;

(iii) carrying out or arranging for the necessary corrective actions when results of quality control test results including those specified in 801.F.10(b)(3) indicate the need; and

(iv) maintenance of records documenting 801.F.10(b)(1)(i) - (iii) above.

(2) Quality Assurance Program Review. At intervals not to exceed 12 months, the registrant shall conduct a review of the effectiveness of the quality assurance program required in (b)(1) and maintain a written report of such review. The two most recent copies of such reports shall be available for inspection by the agency.

(3) Equipment Quality Control Tests. The registrant shall ensure that the following quality control tests are performed when applicable equipment is initially installed and according to the frequency specified, and that applicable tests are performed after major changes or replacement of parts:[5/]

(i) Processor performance by sensitometric means daily, prior to the first patient exposure. For any mammography registrant using film processors at multiple locations, such as a mobile service, each processor shall be subject to this requirement. Corrective action shall be taken when:

(a) deviations of ± 0.15 or more in Optical Density (OD) from established operating levels occur for readings of mid-density (MD) and density difference (DD) on the sensitometric control charts.

(b) base plus fog (B+F) exceeds the established operating level by more than 0.03 OD.

(ii) Screen-film contact and artifact detection - 6 months.

(iii) Screen cleaning - monthly.

(iv) Compression device performance (releases, level of force, etc.) - 6 months.

(v) Image quality (using a test "phantom," which simulates the composition of the breast and includes normal and pathological breast structures) - monthly for stationary systems and prior to performing mammography at each new location for mobile systems.

(vi) Dark dusting of Xerographic plates in positive mode - monthly.

(vii) For receptor speed uniformity (screen-film cassette) - 12 months.

(viii) Collimator alignment - 12 months.

5/Operator/technologist generally performs tests i - vi, Physicist generally performs tests vii - xiv.

(ix) Primary/secondary barrier transmission - upon initial x-ray system installation only.

(x) Resolution and/or focal spot size - upon tube installation or replacement only.

(xi) Half-value-layer - 12 months.

(xii) kVp accuracy - 12 months.

(xiii) Output reproducibility, mA linearity, timer linearity, and mR/mAs - 12 months.

(xiv) Automatic exposure control reproducibility, including kVp response and thickness response - 12 months.

(4) Additional Quality Control Requirements. The registrant shall perform the following observations according to the frequency noted and record the results. Corrections of problems noted shall be made and recorded. Records shall be maintained over the most recent two year period.

(i) Retake rate - 3 months or after 250 patients.

(ii) Viewbox uniformity - 6 months.

(iii) Darkroom integrity - 6 months.

(iv) Adequacy of film storage (including storage after exposure if processing does not occur immediately) 12 months.

(c) Additional Facility Requirements.

(1) Masks. Masks may be provided on the viewboxes to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the film size or area of clinical interest.

(2) Film Processing. Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.

(3) Instrument Calibration. An image quality phantom and calibrated sensitometer, densitometer and thermometer must be available to each facility in order to comply with the quality control test frequencies specified in 801.F.10(b) of this section. The calibration of the instruments must be checked every 12 months.

(4) Operator Qualifications. The operator of the x-ray machine shall be certified by the American Registry of Radiologic Technologists or an equivalent state licensing body and shall have had special training in mammography.

(5) Physician Qualifications. The physician interpreting the mammograms shall be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or Board eligible, or equivalent, and shall have had special training in mammography and image interpretation.

(6) Physicist Qualifications. The person performing evaluation of mammographic system performance in accordance with these regulations shall be certified by the American Board of Radiology or equivalent or be recognized as competent by a state radiation control program.

(7) Image Retention. Clinical images shall be retained for a minimum of 5 years.

(8) Retake Rate. The minimum acceptable retake rate shall be no greater than 5%.

(9) Darkroom Fog. Darkroom fog levels shall not exceed 0.02 OD when sensitized film is exposed to darkroom conditions with safelight on for 2 minutes.

(d) Personnel Responsibilities.

(1) Operator/Technologist.

Daily.

(i) Processor performance in accordance with 801.F.10(b)(3)(i).

Monthly.

(ii) Screen cleaning.

(iii) Image quality in accordance with 801.F.10(b)(3)(v).

(iv) Dark dusting.

Quarterly.

(v) Retake rate.

Semiannually.

(vi) Screen-film contact and artifact detection.

(vii) Compression device performance.

(viii) Viewbox uniformity.

(ix) Darkroom integrity.

Annually.

(x) Adequacy of film storage.

(2) Medical Physicist.

Initially and as specified by the medical physicist.

(i) Primary/secondary barrier transmission.

(ii) Resolution and/or focal spot size.

Annually.

(iii) For receptor speed uniformity.

(iv) Collimator alignment.

(v) Half-value-layer.

(vi) kVp accuracy.

(vii) Output reproducibility, mA linearity, timer linearity, and mR/mAs.

(viii) Automatic exposure control reproducibility, including kVp response and thickness response.

PART 801

SECTION F

APPENDIX A

DETERMINATION OF COMPETENCE

The following are areas in which the agency considers it important that an individual have expertise for the competent operation of x-ray equipment.

I. Familiarization With Equipment.

- A. Identification of controls.
- B. Function of each control.
- C. How to use a technique chart.

II. Radiation Protection.

- A. Collimation.
- B. Filtration.
- C. Gonad shielding and other patient protection devices if used.
- D. Restriction of x-ray tube radiation to the image receptor.
- E. Personnel protection.
- F. Grids.

III. Film Processing.

- A. Film speed as related to patient exposure.
- B. Film processing parameters.
- C. Quality Assurance Program.

IV. Emergency Procedures.

- A. Termination of exposure in event of automatic timing device failure.

V. Proper use of Personnel Dosimetry, if Required.

VI. Understanding Units of Radiation.

PART 801

SECTION F

APPENDIX B

INFORMATION TO BE SUBMITTED BY PERSONS

PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

I. Name and address of the applicant and, where applicable, the names and addresses of agents within this State.

II. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

III. A detailed description of the x-ray examinations proposed in the screening program.

IV. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

V. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.

VI. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures for the x-ray examinations to be performed.

VII. A description of the diagnostic x-ray quality control program.

VIII. A copy of the technique chart for the x-ray examination procedures to be used.

IX. The qualifications of each individual who will be operating the x-ray system(s).

X. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

XI. The name and address of the individual who will interpret the radiograph(s).

XII. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

XIII. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

XIV. An indication of the frequency of screening and the duration of the entire screening program.

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SECTION F

APPENDIX C

EXEMPTIONS FROM SHIELDING FOR CERTAIN FLUOROSCOPIC PROCEDURES

I. Myelograms

II. Arthrograms

III. Angiograms

IV. Percutaneous nephrostomies

V. Biliary drainage procedures

VI. Percutaneous cholangiograms

VII. T-tube cholangiograms

VIII. Sinograms or fistulograms

IX. Fluoroscopic biopsy procedures

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SECTION F

APPENDIX D

Actual (f_{eff}) and Nominal (f_{nom}) Focal Spot Sizes necessary to achieve an Object Plan Spatial Resolution of 12.5 cycles/mm at the Chest Wall

SID (cm)	Magnification	f_{eff} (mm)	f_{nom} (mm)
80	1.07	1.2	0.6
65	1.08	1.1	0.5
50	1.11	0.85	0.4
--	1.5	0.23	0.15
--	2.0	0.15	0.10